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| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>   |  | ATTORNEY'S DOCKET NUMBER<br>31092-05<br>U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>10/521,067</b> |
| INTERNATIONAL APPLICATION NO.<br><b>PCT/US03/22297</b>  | INTERNATIONAL FILING DATE<br><b>17 July 2003</b> | PRIORITY DATE CLAIMED<br><b>17 July 2002</b>   |
| TITLE OF INVENTION<br><b>TREATMENT OF DRY EYE SYNDROME</b>  |  |  |
| APPLICANT(S) FOR DO/EO/US<br><b>THORNTON, Spencer P., et al</b>   |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |  |
| <p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))           <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ul> </p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).           <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ul> </p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))           <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ul> </p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> |  |  |
| <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter. (See Combined Declaration document)</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input checked="" type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). <b>International</b></p> <p>20. <input checked="" type="checkbox"/> Other items or information: <b>Copy of International Preliminary Examination Report ; Search Report</b></p>   |  |  |

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail" Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and addressed to the Director of the United States Patent & Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450

*[Signature]*  
DATE: **1-11-05**  
EXPRESS MAIL NO. **EV 39172973845**

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

|  |              |   |                          |                        |    |                       |    |
|--|--------------|---|--------------------------|------------------------|----|-----------------------|----|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5)  |              | INTERNATIONAL APPLICATION NO.   | ATTORNEY'S DOCKET NUMBER |                        |    |                       |    |
| <b>10/521067</b>   |              | PCT/US03/22297  | 31092-05                 |                        |    |                       |    |
| 21. The following fees are submitted:  |              |   |                          |                        |    |                       |    |
| <input checked="" type="checkbox"/> a) Basic national fee ..... \$300.00<br><input type="checkbox"/> b) Examination fee ..... \$200.00<br><input type="checkbox"/> c) Search fee ..... \$500.00  |              |   |                          |                        |    |                       |    |
| <b>TOTAL OF ABOVE CALCULATIONS =</b> \$1000.00   |              |   |                          |                        |    |                       |    |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.   |              |   |                          |                        |    |                       |    |
| Total Sheets   | Extra sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE                     |                        |    |                       |    |
| - 100 =  | /50 =        |   | x \$250.00               |                        |    |                       |    |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).   |              |   |                          |                        |    |                       |    |
| CLAIMS   | NUMBER FILED | NUMBER EXTRA  | RATE                     |                        |    |                       |    |
| Total claims   | 20           | - 20 = 0  | x \$50.00                |                        |    |                       |    |
| Independent claims   | 3            | - 3 = 0   | x \$200.00               |                        |    |                       |    |
| <b>MULTIPLE DEPENDENT CLAIM(S) (if applicable)</b>   |              |   |                          |                        |    |                       |    |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |              |   |                          |                        |    |                       |    |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.  |              |   |                          |                        |    |                       |    |
| <b>SUBTOTAL =</b> \$150  |              |   |                          |                        |    |                       |    |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).  |              |   |                          |                        |    |                       |    |
| <b>TOTAL NATIONAL FEE =</b> \$150  |              |   |                          |                        |    |                       |    |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property   |              |   |                          |                        |    |                       |    |
| <b>TOTAL FEES ENCLOSED =</b> \$ 190  |              |   |                          |                        |    |                       |    |
| <table border="1" style="width: 100%;"> <tr> <td>Amount to be refunded:</td> <td>\$</td> </tr> <tr> <td>Amount to be charged:</td> <td>\$</td> </tr> </table>  |              |   |                          | Amount to be refunded: | \$ | Amount to be charged: | \$ |
| Amount to be refunded:   | \$           |   |                          |                        |    |                       |    |
| Amount to be charged:  | \$           |   |                          |                        |    |                       |    |
| a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.<br>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>08-0719</u> in the amount of \$ <u>190</u> to cover the above fees. A duplicate copy of this sheet is enclosed.<br>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-0719</u> . A duplicate copy of this sheet is enclosed.<br>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2036. |              |   |                          |                        |    |                       |    |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.   |              |   |                          |                        |    |                       |    |
| SEND ALL CORRESPONDENCE TO:<br><u>John B. Hardaway, III</u><br><u>Nexsen Pruet, LLC</u><br><u>P.O. Box 10107</u><br><u>Greenville, SC 29603</u>  |              |   |                          |                        |    |                       |    |
| <br>SIGNATURE<br><u>J. Herbert O'Toole</u><br>NAME<br><u>31,404</u><br>REGISTRATION NUMBER   |              |   |                          |                        |    |                       |    |
| Date: <u>Jan. 11, 2005</u>   |              |   |                          |                        |    |                       |    |

10/521067

DT Rec'd PCT/PTO 11 JAN 2005

## CERTIFICATE OF MAILING BY FIRST CLASS MAIL (37 CFR 1.8)

Applicant(s): Thornton, Spencer P., M.D. and Troyer, Ellen

Docket No.

31092- 05

Application No.  
PCT/US03/22297

Filing Date

Examiner

Customer No.

Group Art Unit

Invention:

Treatment for Dry Eye Syndrome

I hereby certify that this ASSIGNMENT AND ALL RELATED DOCUMENTS*(Identify type of correspondence)*

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

January 11, 2005  
*(Date)*Kim E. Lang  
*(Typed or Printed Name of Person Mailing Correspondence)*Kim E. Lang  
*(Signature of Person Mailing Correspondence)*

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